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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/307,223	05/07/99	VARNER J	6627-PA11

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EXAMINER	
UNGAR, S	
ART UNIT	**PAPER NUMBER**
1642	5

DATE MAILED: 05/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/307,223	Varner
Examiner	**Group Art Unit**
Unger	1642

☒ Responsive to communication(s) filed on *May 7, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-79* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-79* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Claims 1-79 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions. 2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group I. Claims 1-20, 55-75 are drawn to a method of reducing or inhibiting angiogenesis, classified in Class 514, subclass 2 and Class 424, subclass 130.1

Group II. Claims 21-34 are drawn to a method of identifying the presence of angiogenesis in a tissue classified in Class 514, subclass 2 and Class 424, subclass 130.1.

Group III. Claims 35-46 are drawn to an *in vitro* method of diagnosing a pathological condition, classified in Class 435, subclasses 4 and 7.1.

Group IV. Claims 47-54 are drawn to an *in vivo* method of diagnosing a pathological condition, classified in Class 514, subclass 2 and Class 424, subclass 130.1.

Group V. Claims 76-79 are drawn to a method of identifying an agent that reduces or inhibits angiogenesis classified in Class 435, subclass 4 and Class 514, subclass 2

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I-V are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Group I is further subject to election of a single disclosed species.

Claims 1 and 57 are generic to a plurality of disclosed patentably distinct species comprising tissues with different structures and functions wherein the tissues are (a) ocular tissue (claims 4, 5 and 68-72), (b) skin tissue (claim 6), (c) synovial tissue (claim 7), (d) bone tissue (claim 8), (e) neoplastic tissue (claims 9-12, 58-63), joints (claims 73-75.

If species (a) is elected, the species is subject to election of a single disclosed species.

Claims 4, 5, and 68 are generic to a plurality of disclosed patentably distinct species comprising pathological conditions wherein the condition have different

etiologies, wherein the conditions are (a)(I) diabetic retinopathy, (a)(ii) macular degeneration, both of claim 69.

Claims 4, 5, and 68 are generic to a plurality of disclosed patentably distinct species comprising methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the methods of administration differ wherein the methods comprise (a) administered as eye drops (claim 70), (b) administered IV (claim 71), (c) administered orally (claim 67).

If species (e) is elected, the species is subject to election of a single disclosed species.

Claims 57 and 58 are generic to a plurality of disclosed patentably distinct species comprising neoplasms with different etiologies comprising (e)(I) a benign neoplasm (claim 58), (e(ii) a malignant neoplasm, including a carcinoma (claims 59, 61, 62), (e)(iii) metastatic malignant neoplasm including (claims 60), (e)(iv) a sarcoma (claim 63), (e)(v) a mesothelioma (claim 63), (e)(vi) a teratocarcinoma (claim 63), (e)(vii) an astrocytoma (claim 63), (e)(viiii) a glioblastoma (claim 63).

6. Group I is further subject to election of a single disclosed species.

Claim 57 is generic to a plurality of disclosed patentably distinct species comprising methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the methods of administration differ wherein the methods comprise (a) administered IV (claim 65), (b) administered orally (claim 66), (c) administered

intraneoplasm (claim 67). Claim 67 will be examined only if the species of a neoplasm is elected.

7. Group I is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising agents with different structures and functions wherein the agent comprises (a) a peptide (claims 13, 14), (b) an antibody (claim 15), (c) a nonpeptide organic molecule (claims 16-18). If species (c) is elected applicant is required to specifically elect one of the nonpeptide organic molecules recited in claims 17 and 18.

8. Group II is further subject to election of a single disclosed species.

Claim 21 is generic to a plurality of disclosed patentably distinct species comprising agents with different structures and functions wherein the agent comprises (a) a peptide (claims 22-23), (b) an antibody (claim 24), (c) a nonpeptide organic molecule (claims 25-27). If species (c) is elected applicant is required to specifically elect one of the nonpeptide organic molecules recited in claims 26 and 27.

9. Group II is further subject to election of a single disclosed species.

Claim 21 is generic to a plurality of disclosed patentably distinct species comprising tissues with different structures and functions wherein the tissues are (a) embryonic tissue (claim 30), (b) placental tissue (claim 30), (c) granulation tissue (claim 31), (d) tissue involved in a pathological condition (claims 32-32 and 33), (e) ocular tissue (claims 34).

10. Group III is further subject to election of a single disclosed species.

Claim 35 is generic to a plurality of disclosed patentably distinct species comprising pathological conditions in different tissues wherein the pathologies have different etiologies and paths of pathenogenesis wherein the pathologies are (a) pathological conditions involving eye including diabetic retinopathy (claims 36 and 37), (b) pathological conditions involving eye including macular degeneration (claims 36 and 37), (c) pathological conditions involving skin including hemangioma (claims 38 and 39), (d) pathological conditions involving skin including psoriasis (claims 38 and 39), (e) pathological conditions involving joint including rheumatoid arthritis (claims 40 and 41), (f) pathological conditions involving joint including osteoarthritis (claims 40 and 41), (g) pathological conditions involving a neoplasm including a malignant neoplasm, including a carcinoma (claims 42, 43 and 45), (h) pathological conditions involving neoplasm including metastatic malignant neoplasm including (claims 42-44). If species (g) is elected, the species is subject to election of a single disclosed species comprising types of carcinomas with different etiologies wherein the carcinomas are (a) breast, (b) colon, © ovarian, (d) pancreatic, all of claim 46.

11. Group IV is further subject to election of a single disclosed species.

Claim 47 is generic to a plurality of disclosed patentably distinct species comprising in vivo imaging methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the methods are (a) radionuclide imaging, (b) positron emission tomography, (c) computerized axial tomography, (d) MRI.

12. Group IV is further subject to election of a single disclosed species.

Claim 47 is generic to a plurality of disclosed patentably distinct species comprising methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the methods comprise (a) *in vivo* detection of binding (claims 47-51) and (b) obtaining a sample from the patient to whom a binding agent had been administered (claims 52-53).

13. Group V is further subject to election of a single disclosed species.

Claim 75 is generic to a plurality of disclosed patentably distinct species comprising methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the methods comprise contacting tissue (a) in vivo (claim 77), (b) ex vivo (claim 78).

14. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship

must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

16. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
May 8, 2000